**PHYSIODISC STE**

**STERILE Cervical disc prosthesis**

**INSTRUCTIONS FOR USE**

1. **INTRODUCTION**

   The Physiodisc cervical disc prosthesis makes it possible to restore disc height and to preserve mobility between two vertebras.

   Fastening to bone is done by a primary block fixation system combined with a porous titanium coated surface for secondary fixation.

   The prosthesis consists of three components: a cobalt chrome upper plate, a cobalt chrome lower plate and a polyethylene core.

2. **DESCRIPTION OF MATERIAL**

   The 3 components of PHYSIODISC prosthetic cervical spine discs are secured using a plastic component.

   In addition, this item makes it possible to handle the prosthetic disk up until its installation in the impactor grasper instrument.

   The PHYSIODISC is supplied in the following product range:

   - in several heights to fit the opening of the vertebral foramen;
   - in several widths and lengths to fit the patient’s anatomy and to provide good stability;
   - The outline of the metal plate enables X-ray identification of placement of the PHYSIODISC.

   A dedicated instrument kit is supplied with the prosthetic disk to facilitate its installation.

3. **INDICATIONS**

   - Patients 25 to 55 years of age for whom surgery can be proposed.
   - C5-C7 vertebrae.
   - Symptoms of neck pain with or without associated radiculalgia.
   - Symptoms of cervico-brachial neuralgia.
   - Symptoms of cervico-osteoarthritis myelopathy.

   **MATERIAL:**

   - The PHYSIODISC prosthetic plates are made of Cobalt Chrome (specification ISO 5832-12), coated with Titanium T40 (current specification ASTM F1580). The core is made of UHMWPE polyethylene (ISO 5834-2 specification).
   - The instrument is made of non-implantable stainless steel.
   - The presentation tray is made of Ultem.

4. **CONTRAINDICATIONS**

   - Severe cervical spinal stenosis.
   - Advanced articular osteoarthritis.
   - History of infection.
   - Vascular problem of carotid artery disease.
   - Major degenerative or constitutional vertebral instability.
   - Immunodeficiency disease (including HIV).
   - Known and treated severe osteoporosis.
   - Paget’s disease, osteomalacia, bone metabolic disorder.
   - Pregnancy.
   - Malignant tumour.
   - Allergy or intolerance to Chrome, Cobalt, Titanium, Molybdenum or Polyethylene.

5. **CONDITIONS FOR STORAGE**

   - Store in its original package.
   - In a clean, dry place.
   - Away from UV radiation.

   Verify the integrity of all aspects of the packaging, if damaged DO NOT use.

   Avoid shock to or crushing of the box.

6. **INFORMATION / WARNING**

   - Implants are for single use only and are delivered STERILE. They are sterilised by gamma radiation.
   - Any implant which has been implanted cannot be reused. Depending on duration of implantation, the upper level of the material undergoes alteration and its mechanical properties no longer will be the same.
   - In case of an error in use, the implant is not designed for mechanical cleaning without risk of deterioration.
   - In such a case, residual contamination of the implant cavity will not make it possible to ensure device safety.
   - Implants are supplied in unit packages allowing aseptic presentation.

   If any aspect of the packaging is damaged, sterility cannot be guaranteed. Use of the implant is then under the total responsibility of the user.

   - Re-sterilisation of an implant by any method is prohibited. There is a risk of deterioration of the material during a second sterilisation (gamma radiation + other method) and this risk is not controlled.
   - Compliance with pre-operative and peri-operative procedures, including knowledge of surgical techniques, adequate reduction, as well as proper selection and positioning of implants are important factors in successful use of the system by the surgeon. In addition, appropriate selection of patients and cooperation of the latter greatly affect results. It has been demonstrated that patients who are smokers will tend to have less optimal consolidation in spinal fusion surgery.

7. **PRECAUTIONS TO OBSERVE**

   a) Prior to surgery

   - Read the surgical instructions carefully.
   - Check the integrity of implant kit.
   - Prepare all bone implants and instruments necessary for the procedure.
   - Loss of vacuum (re-swelling of sachets) indicates loss of air tightness. In such a case DO NOT use the implants.
   - Handle implants with care to prevent deep scratches (risk of start of rupture).
   - Evaluate size and number of implants to install based on a preoperative radiograph.
   - After taking measurements, plan to have implants of different planned sizes in order to have a sufficient choice among them.
   - Always plan to have an extra implant of each planned size in order to replace it in case of accidental contamination during the procedure.
   - Only instruments for implant placement, studied and provided by KISCO International, should be used in association with the implant.
   - Before installing a bone implant for the first time, the surgeon and his surgical team should practice handling the instruments to become familiar with the equipment.

   b) During surgery

   - The fire procedure should be performed by a surgeon who has received the necessary training in spinal surgery.

   Keep to the different phases described in the surgical technique.

   Sudden spreading apart can produce the following:

   - oedema,
   - traction on the upper laryngeal nerve producing a two-tone voice.

   Peri-operative bleeding from an epidural vein must necessarily be managed by gentle application of haemostatic swabs or bipolar coagulation under microscope control.

   Use an imaging intensifier to check the position of the test implant and of the final implant.

   In case of dislocation of the prosthesis and difficulty in reassembling, use another prosthesis.

   Implantation of an implant should be done solely with the instruments provided for this purpose and according to indications of the surgical technique.

   c) After surgery

   - Radiological examinations must be performed regularly to check on post-operative progress and prevent possible complications.

8. **UNDESIRABLE EFFECTS**

   - Displacement or expulsion of the implant before bone fusion requiring another surgical procedure.
   - Infection of the implantation site.
   - Risk of allergy to Cobalt-Chrome, Molybdenum, titanium, or Polyethylene are rare but should be taken into account before the procedure.

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**5 years**

[Image: KISCO Logo]